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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,493	06/24/2005	Dominique Giorgi	1169-036	7207

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EXAMINER	
MONDESI, ROBERT B	
ART UNIT	PAPER NUMBER
1652	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	02/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,493	GIORGI ET AL.	
	Examiner	Art Unit	
	Robert B. Mondesi	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) 28-58 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 28-58 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-27 have been canceled. **Claims 28-58** are new. **Claims 28-58** are currently pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 28 (in part, as far as section a) is concerned) 29 and 38, drawn to an ASAP contained in a medicinal product.

Group II, claim(s) 28 (in part, as far as section d-g) are concerned) 30, 41-42, and 44-45 drawn to a nucleic acid encoding an ASAP protein contained in medicinal product.

Group III, claim(s) 28 (in part, as far as section b) is concerned) 31 and 39 drawn to a peptide contained in a medicinal product.

Group IV, claim(s) 28 (in part, as far as section c) is concerned) 32 and 40 drawn to a monoclonal or polyclonal antibody capable of specifically recognizing an ASAP protein.

Group VI, claim(s) 33, drawn to a method of preparing an anti-mitotic medicinal product.

Group VII, claim(s) 34, drawn to a method of preparing a medicinal product for treating pathologies associated with disturbances in mitotic spindle organization or with induction of aberrant and abortive mitoses associated with over-expression of ASAP protein.

Group VIII, claim(s) 35 and 36, drawn to a method of diagnosing pathological states or genetic diseases associated with disturbances in mitotic spindle organization or cell division anomalies or both, which comprises probing for said states or diseases or both with a polynucleotide.

Group IX, claim(s) 37, drawn to A method of detecting or selecting cells or both exhibiting disturbances in mitotic spindle organization or induction of aberrant and abortive mitoses associated with over-expression of a protein, which comprises detecting or selecting cells using an antibody.

Group X, claim(s) 43, drawn to a primer for amplifying a polynucleotide.

Group XI, claim(s) 46 and 47, drawn to a non-human transgenic animal.

Group XII, claim(s) 48-50 and 53 drawn to a method for diagnosing a pathological state associated with disturbances in mitotic spindle organization or with cell division anomalies or both, which comprises determining an alteration of a transcription profile of the gene encoding the ASAP protein comprising at least the steps of: a) a first step of obtaining a total RNA from a biological sample, b) a second step of bringing said RNA into contact with a probe, labeled beforehand, under conditions for hybridization between the RNAs and the probe, and c) a third step of detecting the hybrids formed.

Group XIII, claim(s) 51-52 and 54 drawn to a method for diagnosing a genetic disease associated with disturbances in mitotic spindle organization or with cell division anomalies or both, which comprises demonstrating a functional alteration of the gene encoding the ASAP protein, according to at least the following steps: a) a first step of obtaining DNA from a biological sample, b) a second step of bringing said DNAs into contact with a probe labeled beforehand, under conditions for hybridization between the DNAs and the probe, and c) a third step of detecting the hybrids formed.

Group XIV, claim(s) 55 and 57, drawn to a method for evaluating, in vitro, a proliferative capacity or aggressiveness of cancer cells, comprising: a) a first step comprising treating cells for making the intracellular medium accessible, b) a second step comprising bringing said intracellular medium thus obtained into contact with an antibody, c) a third step comprising the ASAP protein-antibody complex formed, and d) a fourth step comprising evaluating the level of transcription of the gene by comparison of the level of ASAP protein-antibody complexes formed with that of a control biological sample selected beforehand.

Group XV, claim(s) 56 and 58, drawn to a method of screening for a substance capable of modulating the activity of the protein: a) in a first step, cells of a biological sample expressing a protein, are brought into contact with a substance to be tested, b) in a second step, the effect of said substance on mitotic spindle organization or the induction of aberrant and abortive mitoses is measured, and c) in a third step, substances capable of modulating said activity are selected.

The inventions listed as Groups I-XV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-XV appears to be that they all relate to an ASAP polypeptide.

However, WO 02/070539 (cited in the IDS filed June 24, 2005) discloses ASAP polypeptides.

Therefore the technical feature linking the inventions of Groups I-XV does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Accordingly, Groups I-XV are not so linked by the same or a corresponding special technical feature as to form a single inventive concept.

Restriction Requirement Applicable to all Groups

Furthermore, the presence of multiple polypeptide sequences and polynucleotide sequences, each with a different SEQ ID NO: allows for a variety of patentably distinct products. Depending on the sequence of each polypeptide and polynucleotide, the characteristics of the resulting molecule will vary in regards to structure and function. Each one of these polypeptides is capable of eliciting a specific immune response and can be used to produce a specific antibody; also each one of the mentioned polynucleotides is capable of hybridizing to different probes and is capable of encoding a characteristically different peptide in regards to structure and activity. Therefore these polypeptides and polynucleotides are patentably distinct absent factual evidence to the

contrary. Rejoinder of all or a specified subset of the sequences is possible if Applicants provide a single and specific representative subsequence found in all or a specified subset of the sequences for search, and state that all or a specified subset of the sequences are not patentably distinct. Applicants are informed that if their specified sequence is found that all or a specified subset of sequences are obvious over that prior art sequence.

Applicant is required under 35 U.S.C. 121 to elect a single SEQ ID NO: for prosecution on the merits. The applicant should be aware that selection of a single SEQ ID NO: represents a response to a restriction requirement of a patentably distinct product, not an election of species.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert B Mondesi
Examiner
Art Unit 1652

1-27-07